PATENT APPLICATION

AMENDMENT UNDER 37 C.F.R. § 1.111
U.S. Application No. 10/004,873

REMARKS

Upon entry of the above amendments, claims 1-12 and 21-26 are all the claims pending in the application.

Turning now to the instant Office Action, the Abstract of the Disclosure stands objected to, as M.P.E.P. § 608.01(b) requires the Abstract to be less than 150 words. Applicant has obviated this objection by replacing the Abstract as shown above.

I. Rejection of Claims 1-12 Under 35 U.S.C. § 112, second paragraph

Claims 1 - 12 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. More specifically, the Examiner, provides six section 112 rejections to the claims as indicated on pages 3 and 4 of the instant Office Action. Some of these rejections apply to all of the claims and some of these rejections apply to sub-sets of the claims. Applicant has amended the claims, to deal with these rejections as follows:

(1) adding the phrase "image analysis" to independent claim 1;
(2) changing "spot-like dropping" to "dropping spots of . . ." throughout the claims;
(3) changing "effecting quantitative analysis" to "performing quantitative image analysis" throughout the claims;
(4) amending claims 2 – 12 to clarify additional steps in the method;
(5) amending claims 6 – 8 to clarify the use of the polymer; and
(6) correcting for lack of antecedent basis in claims 11 and 12 as to "the substance derived from a living organism."

In light of the previous, the Examiner is respectfully requested to reconsider and withdraw the above-noted rejections.

II. Rejection of Claims 1, 2, and 10 Under 35 U.S.C. §§ 102(a) and 102(e)

Turning now to the alleged anticipation rejections, claims 1, 2 and 10 stand rejected under 35 U.S.C. §§ 102(a) and 102(e) as allegedly being anticipated by U.S.P. No. 6,160,618 ("Garner"). Applicant respectfully traverses this rejection as follows.

Independent claim 1 recites dropping spots of a specific binding substance onto a substrate to form a plurality of spots, photoelectrical detection of the plurality of spots to produce template data, producing a template based on the template data, the template being used for defining areas of interest for quantification and then performing quantitative image analysis based on the template.

To the extent that Garner teaches hybridization of a chromosome 11 filter (cols. 10 - 11) and hyperspectral imaging therefore, it is not clear that Garner further teaches setting a region of interest based on grids of dot arrays. In particular, the hyperspectral imaging of Garner allows coordinates to be determined in X-Y and wavelength coordinates, thereby obviating the need to separately delineate a region of interest from a dot array. Therefore, Garner not only explicitly fails to suggest defining a region of interest for the dot array but specifically teaches away from the definition of such a region in favor of error free spot-addressing made available by hyperspectral images.

Additionally, while col. 8, lines 53 - 66 of Garner may discuss dropping spots on a slide to produce a "master coordinate grid" (*see* col. 11, lines 3 - 4), Garner absolutely fails to teach or suggest the creation of template *data*. Accordingly, Garner fails to teach or suggest "producing

template *data*" as claimed in independent claim 1.

As to claim 2, Garner fails to teach or suggest the use of a fluorescent dye for producing a template capable of being stimulated by a stimulating ray having a different wavelength from that of a stimulating ray capable of stimulating a fluorescent dye labeling a target substance derived from a living organism onto a substrate together with a specific binding substance to form a plurality of spots, and then irradiating the plurality of spots to create template data. That is, while Garner may disclose something similar to the use of a template (*see* col. 11, lines 1 - 12), Garner does not disclose the creation of template *data* for defining a region of interest.

As to claim 3, claim 3 depends from claim 2, thereby incorporating all the limitations of claim 2. Accordingly claim 3 recites at least two fluorescent dyes that respond at different wavelengths of irradiating light, wherein a first fluorescent dye fluoresces as a label for a target substance derived from a living organism and a second fluorescent dye fluoresces for the purpose of producing template data. Moreover, claim 3 recites first and second stimulating rays, as well as first and second photoelectrical detection. These features are neither taught nor suggested by the Garner reference in the claimed combinations.

As to claim 4, claim 4 depends from claim 2, thereby incorporating all the limitations of claim 2. Accordingly claim 4 recites at least two fluorescent dyes that respond at different wavelengths of irradiating light, wherein a first fluorescent dye fluoresces for the purpose of producing template data and a second fluorescent dye fluoresces as a label for a target substance derived from a living organism to produce image data. Moreover, claim 4 recites first and

second stimulating rays, as well as first and second photoelectrical detection. Additionally, claim 4 recites hybridization of a substance derived from a living organism and labeled with a fluorescent dye with the specific binding substance prior to the irradiation/detection. These features are neither taught nor suggested by the Garner reference in the claimed combinations.

As to claim 5, claim 5 depends from claim 2, thereby incorporating all the limitations of claim 2. Accordingly claim 5 recites at least two fluorescent dyes that respond at different wavelengths of irradiating light, wherein a first fluorescent dye fluoresces for the purpose of creating template data and a second fluorescent dye fluoresces as a label for a target substance derived from a living organism to produce image data. Moreover, claim 5 recites first and second stimulating rays, as well as first and second photoelectrical detection, wherein hybridization is performed between the first and second detection. These features are neither taught nor suggested by the Garner reference in the claimed combinations.

As to claim 6, claim 6 recites the fluorescent dye for producing template data being contained in a polymer. This feature is neither taught nor suggested by the Garner reference.

As to claim 7, claim 7 depends from claim 6 (and therefore from claim 2), wherein the step of dropping the specific binding substance includes dropping the polymer to create the plurality of spots, and wherein hybridization occurs prior to irradiation/detection. These features are neither taught nor suggested by the Garner reference in the claimed combinations.

As to claim 8, claim 8 is similar in nature to claim 7, but wherein the first and second irradiation/detection are reversed. Applicant respectfully traverses this rejection for reasons

analogous to those reasons enumerated for claim 7.

As to claim 9, claim 9 recites a first and second plurality of spots, between which a first irradiation/detection occurs for producing template data. Applicant respectfully traverses this rejection based on this claimed combination.

As to claim 10, claim 10 depends from claim 1, thereby incorporating all the limitations of claim 1. Accordingly, claim 10 includes the feature of photoelectrical detection of the plurality of spots to create template data. The Garner reference fails to teach or suggest the creation of template data. Applicant respectfully traverses this rejection for this additional reason.

As to claim 11, claim 11 recites hybridization prior the first and second irradiation/detection. Applicant respectfully traverses this rejection based on the claimed combinations.

As to claim 12, claim 12 recites hybridization prior a first and second irradiation/detection, wherein the first and second irradiation/detection is reversed as compared to claim 11. Applicant respectfully traverses this rejection based on the claimed combinations.

III. Rejection of Claims 1-12 Under 35 U.S.C. § 102(b)

Turning now to the second 35 U.S.C. § 102(b) rejection, claims 1 – 12 stand rejected as allegedly being anticipated by U.S.P. No. 6,100,030 ("Feazel *et al.*"). Applicant respectfully traverses this rejection because the Feazel reference fails to teach or suggest the creation of template *data* or the use of a *template for defining regions of interest.* The Examiner's reliance

on cols. 37 - 39 to teach features of the invention do not indicate how a template is formed. For example, a sample is provided for all populations of a sample, and average luminescence is determined. It is not inherent that a template is created, however, or that a region of interest be defined. Accordingly, the Examiner is respectfully requested to reconsider and withdraw this rejection.

III. Rejection of Claims 3-9 and 11-12 Under 35 U.S.C. § 103(a)

Turning now to the 35 U.S.C. § 103(a) rejection, claims 3 - 9 and 11 - 12 stand rejected as allegedly being obvious in view of a combination of Garner and Feazel. Applicant respectfully traverses this rejection because "any claim which depends from a non-obvious claim is therefore non-obvious." *See* M.P.E.P. § 2143.03. Accordingly, at least because the claims that are rejected depend from claims that are themselves non-obvious, claims 3 – 9 and 11 – 12 are also non-obvious. Moreover, neither Garner nor Feazel teach or suggest the instant invention in the claimed combinations, such as previously discussed in relation to the above-noted § 102 rejections.

Claims 21 - 26 have been added which recite additional features of the invention. These claims are averred to be patentable at least by virtue of their dependency upon independent claim 1, wherein independent claim 1 is averred to be patentable reasons stated in Parts I and II of this paper.

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IV. Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

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CUSTOMER NUMBER

Date: January 21, 2004

CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this AMENDMENT UNDER 37 C.F.R. § 1.111 is being facsimile transmitted to the U.S. Patent and Trademark Office this 21st day of January, 2004.

Thea K. Wagner